

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Roland Callens et al.

Application No.: 10/551,723

Confirmation No.: 5795

Filed: February 14, 2006

Art Unit: 1621

For: PROCESS FOR PRODUCING ENANTIOPURE  
β-AMINO ACID DERIVATIVES, AND  
ENANTIOPURE β-AMINO ACID  
DERIVATIVES

Examiner: K. J. Puttlitz

**1.132 DECLARATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

1. I, Cyrille Pousset, am French citizen residing at Rue de Sévigné 29, 1070 Brussels, Belgium. I hold a Ph.D. degree in Organic Chemistry and I am employed by Peptisyntha, an affiliate company of Solvay SA, since 2003 as researcher.
2. I am one of the named inventors of this application, U.S. Application No.: 10/551,723 ("723 application").
3. In view of my qualifications as outlined above, I consider myself to be an expert and to be skilled in the amino acid field.
4. I have read and reviewed the '723 application.
5. Under my supervision I had the following experiment conducted:
6. I have subjected 1mmole of racemic β-amino ester derivative of formula (VI) to hydrolysis in the presence of 500mg of *Candida Antarctica* lipase B at a temperature of 30°C and pH of 7 in a reaction medium comprising in addition 10 ml pH 7 phosphate buffer and 1ml ethanol.
7. After 81 hours of reaction I have determined the enantiomeric excess of the β-amino acid produced and of unconverted β-amino acid ester. The enantiomeric excess of the β-amino acid produced was 60% and the enantiomeric excess of the unconverted β-amino acid ester was 76%. The chemical yield of the β-amino acid produced was 49% and the chemical yield of the unconverted β-amino acid ester was 23%.

8. In example 1 of the current patent application the enantiomeric excess of the  $\beta$ -amino acid produced was 99% and the enantiomeric excess of the unconverted  $\beta$ -amino acid ester was 99%.
9. Thus enantiomeric purity of the enantiopure  $\beta$ -amino acid derivatives obtained by hydrolysis with *Pseudomonas Cepacia* according to example 1 of the current patent application is unexpectedly better than with the *Candida Antarctica* lipase B. Also the chemical yield of enantiopure  $\beta$ -amino acid ester is unexpectedly better in example 1 than in the comparison according to point 2.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Cyrille Pousset

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Date



C.POUSSET

September 2, 2008